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SECTION 8

SUMMARY OF SAFETY AND EFFECTIVENESS

510(k) Summary of Safety and Effectiveness	Information supporting claims of substantial equivalence, as defined under the Federal Food, Drug and Cosmetic Act, respecting safety and effectiveness is summarized below. For the convenience of the Reviewer, this summary is formatted in accordance with the Agency's final rule "...510(k) Summaries and 510(k) Statements..." (21 CFR 807) and can be used to provide a substantial equivalence summary to anyone requesting it from the Agency. New DEVICE NAME: CardioVations Portable Video System PREDICATE DEVICES NAME: Karl Storz Endoscopy Endovision Telecam SL
Contact	Peter Cecchini Manager, Regulatory Affairs ETHICON, Inc. Rt. #22, West Somerville, NJ 08876-0151 Telephone: 908-218-2457
Date	July 24, 2003
Device Name	Classification Name: Accessory to an endoscope Common Name: Endoscopic Camera System Proprietary Name: CardioVations Portable Video System
Device Description	The CardioVations Portable Video System is a self contained system that is used as an endoscopic accessory to provide visualization during any endoscopic procedure that requires a viewing distance up to 2 inches (5 cm), when

Continued on next page

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SUMMARY OF SAFETY AND EFFECTIVENESS (Continued)

Device Description (Con't)

used with many B-style eyecup rigid endoscopes. The system consists of the following components:

- Video System Controller (Pack)
- Camera Heads (PAL, NTSC) with Light Source and Cable (Umbilical)- as one unit
- Heads-up Display (serves as a monitor or can be connected to a monitor).
- Battery Charger and Universal Power Supply

There are three main components of the CardioVations Portable Video System. These components are the Video System Controller (camera control unit) that is powered by a lithium ion rechargeable battery pack and worn by the user under the sterile gown, a Video Display (Heads-Up Video Display or standard monitor display) description and camera head (two, NTSC or PAL) and compact light source and cable. Only the camera head, light source and connection cable can be sterilized.

The Video System Controller provides power to the camera head and light source through the umbilical cable. The camera and light source is connected to an endoscope for visualization. In use, the camera, light source and cable are brought to the sterile field after being sterilized. The user connects them to a sterile endoscope and passes the cable off to a circulating nurse using appropriate sterile technique. The circulating nurse connects the cable to the control unit and turns the power on. The user then focuses the camera and white balances the unit by pressing the push and lock white balance button. The camera control unit and batteries are designed to be reused indefinitely, while the camera head can be reused 34 times before it needs to be replaced.

Intended Use

The CardioVations Portable Video System is intended to be used as an accessory in any endoscopic procedures that require a viewing distance up to 2 inches (5cm), when used with many rigid B-Style (32mm diameter eyecup) endoscopes.

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SUMMARY OF SAFETY AND EFFECTIVENESS (Continued)

Indications Statement	The CardioVations Portable Video System is designed to be used as an accessory in any endoscopic procedures that require a viewing distance up to 2 inches (5cm), when used with many rigid B-Style (32mm diameter eyecup) endoscopes.
Technological Characteristics	The new device has similar technological characteristics as the predicate device. Both the new and the predicate device are video cameras intended as endoscopic accessories. Both devices can be connected to a monitor to provide visualization of the surgical field. The new device is battery operated with a portable camera controller that can be worn by the user. The predicate device is powered by line voltage and the controller is mounted on a cart in the operating room.
Performance Data for New Device	The CardioVations Portable Video System will be tested compliance with the electrical standards, International Electrotechnical Commission, IEC 60601-1-2 and IEC 60601-2-18, Particular Requirements for Safety of Endoscopic Equipment. Pre-clinical testing was conducted to demonstrate that the CardioVations Portable Video System performed as clinically intended. In a pre-clinical evaluation , the essential performance characteristic assessed was the ability of the system to produce a quality video image in terms of color, clarity, brightness and contrast. The results of the testing concluded that video image quality of the new device is comparable to the predicate device.
Conclusion	Based on the 510(k) summaries and 510(k) statements (21 CFR 807) and the information provided herein, we conclude that the new device is substantially equivalent to the Predicate Devices under the Federal Food, Drug, and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 8 2003

Ethicon, Inc.
c/o Mr. Robert Mosenkis
President
Citech
5200 Butler Pike
Plymouth Meeting, Pennsylvania 19462-1298

Re: K032339
Trade/Device Name: CardioVations Portable Video System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: July 28, 2003
Received: July 29, 2003

Dear Mr. Mosenkis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K032339

Device Name: CardioVations Portable Video System

Indications for Use: The CardioVations Portable Video System is designed to be used as an accessory in any endoscopic procedures that require a viewing distance up to 2 inches (5cm), when used with many rigid B-style (32mm diameter eyecup) endoscopes.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The Counter Use
(Per 21 CFR 801.109)

(Optional Format 1-2-9G)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K032339